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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,940	12/19/2000	Stephen J. Fonash	823.0052USQ	4788

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/15/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/739,940	Applicant(s) FONASH ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 22-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant is informed that at the time this office action is written the parent application (09/580,105) was not made available to the examiner.

The examiner has noted that the method of detection in this invention is drawn to that of laser desorption/ionization time of flight mass spectroscopy.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-21) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I-III are distinct. But they are not independent. Applicant contends that the features (e.g. characteristics of thin film) of the dependent claims in Group I are also found in Groups II and III. Applicant argues that the searches for all three groups are not burdensome. This is not found persuasive because one of the two criteria for a proper requirement for restriction between patentably distinct inventions is that the inventions must be independent **or** distinct (see MPEP 803 under Criteria for restriction). However, Groups I-III are independent inventions. Each group is a different method of detection which involves different method steps. Group I is drawn to *a method of detecting a sample*. Group II is drawn to *a method for selective adherence and detection of an analyte*. Group III is drawn to *a method for analyzing a chemical reaction*. Dependent claims of Group I are **not** relied upon as criteria in the restriction requirement. Although there are some overlapping features (e.g. deposited thin film and detection means) among these inventions, Group I-III, the search requirement for the method steps is **not** coextensive that a search for one invention would **not encompass** the limitations of the other inventions thus resulting in divergent

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of the search evaluations. The search and examination of all three inventions would be burdensome. Therefore, it is the examiner's position that Groups II and III are not to be rejoined with Group I.

The requirement is still deemed proper and is therefore made **FINAL**.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor specifically Mr. Joseph Cuiffi.

Drawings

3. The drawings are objected to because in figure 15 the title of the graph states that it is figure 4. In figure 16, the title of the graph states that it is figure 5. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. A statement reading, "This is a continuation-in-part of Application No. 09/580,1055, filed 5/30/2000." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- M* a) The phrase “analysis of a sample” of claim 1 is vague and indefinite. It is unclear what is the sample being analyzed for? A “sample” can be a piece of wood and it can be analyzed for its content or structure, which are not supported by the enabling written description in the specification.
- M* b) Claim 1 is vague and indefinite in that there is no method steps in the detection of the sample. It also lacks contacting and correlation steps in the detection of the sample. Does it involve a specific binding partner? A signal? Is labeling involved?
- c) Claims 2, 4, and 19 contain improperly written Markush language. When using the phrase “selected from the group consisting of”, “and” is included not “or”.
- d) Claim 3 contains improperly written Markush language. The language used should be “selected from the group consisting of” instead of “obtained from”.
- e) It is unclear what the correlation of claim 5-6 with claim 1 is in regard to the “substrate” and “continuous void”. In what way does this affect the analysis of a sample? Does the sample react with the “substrate”? Does a “continuous void” pertain to the position of the sample?

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- f) It is unclear what the correlation is between claim 8 with regard to the analysis of the sample of claim 1.
- g) The term "film" of claim 10 and 11 lack antecedent basis.
- h) Is the deposited film of claim 1 the same as the deposited film of claims 19-21? That is, is the deposited film used in the separation of the sample then for the sample analysis?
- i) The term "electrical separation means" in claim 18 is the same as the term "separation means" of claim 19.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- M
8. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an analyte detection process by laser desorption/ionization time of flight mass spectroscopy (pg. 22-38), does not reasonably provide enablement for the scope encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim. What part of the sample is being analyzed? Structures? Contents? How is the sample being detected? Does it involve a binding partner? A label? Are multiple analytes of a sample being detected at the same time or just a single analyte?

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The specification does not provide an enabling written description to support the “analysis” of all possible types of “samples” by all possible “detection means”.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bogart (US Patent 5,552,272).

Bogart disclosed a method of analyzing a sample (col. 5, lines 40-42; col. 7, lines 60-62). The method steps include applying a sample to the deposited thin film (optically active surface) (col. 5, lines 43-45; col. 7, lines 63-66) and analyzing the sample by a detection mean (col. 5, lines 45-49; col. 8, lines 4-7). The method of Bogart includes all of the required elements of the method step of the instant claim 1.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dale et al (*Analytical Chemistry*, 1996, 68(19):3321-3329).

Dale et al. disclosed a method of analyzing a sample (abstract). The method steps include applying a sample to the deposited thin film (graphite/liquid matrix layer) (pg. 3323, right col., lines 4-7) and analyzing the sample by a detection mean (pg. 3322, left col., lines 34-

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35). The method of Dale et al. includes all of the required elements of the method step of the instant claim 1.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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15. Claims 1-13 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bogart (US Patent 5,552,272) in view of Ebersole et al. (US Patent 5,658,732).

Bogart disclosed a method of analyzing a sample (col. 5, lines 40-42; col. 7, lines 60-62). The method steps include applying a sample to the deposited thin film (optically active surface) (col. 5, lines 43-45; col. 7, lines 63-66) and analyzing the sample by a detection mean (col. 5, lines 45-49; col. 8, lines 4-7). The sample comprise of protein, lipids, metal, or nucleic acid (col. 27, line 17-22). The sample is obtained from a preparation system (col. 46, line 18-20; col. 48, line 37-42). The deposited thin film is a continuous film that has optical properties (col. 14, line 23-30). A pattern is created on the film by either stamping or printing (col. 29, line 13-15). The film can also be modified in order to attach the sample (col. 7, line 32-34; col. 28, line 1-13). The sample can be detected by antigen-antibody recognition reaction, colorimetric detection, enzyme reaction, chemical detection, or optical detection (col. 5, line 45-49; col. 9, line 19-25 and 34-36). The sample is applied directly to the surface of the film (col. 7, line 35-38; col. 35, line 45-49; fig. 10, step 1; col. 59, line 60-66).

Bogart differs from the claimed invention in failing to disclose the deposited thin film to be a columnar-void film.

Ebersole et al. disclosed a columnar-void film used as a biosensor detector (fig. 1; col. 7, line 33-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Bogart by including a columnar-void film as taught by Ebersole et al. for the practical advantage of providing the same surface to be used for analysis of multiple analytes regardless of the type of analyte (Ebersole et al.: col. 4, line 42-45).

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The features of remaining dependent claims are either well known alternative methods (see US Patent 4,384,957) for analyte purification (e.g. separation means (claims 18)), or constitute obvious variations in parameters which are routinely modified in the art (e.g. type of substrate (claim 6) or film (claim 7); deposition parameters (claim 8)) and which have not been described as critical to the practice of the invention.

16. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dale et al (*Analytical Chemistry*, **1996**, 68(19):3321-3329) in view of Ebersole et al. (US Patent 5,658,732).

Dale et al. disclosed a method of analyzing a sample (abstract). The method steps include applying a sample to the deposited thin film (graphite/liquid matrix layer) (pg. 3323, right col., lines 4-7) and analyzing the sample by a detection mean (pg. 3322, left col., lines 34-35). The sample comprise of peptides (pg. 3323, right col., line 19-21). The deposited thin film is a continuous film that has the property of laser-light reflection (pg. 3322, left col., line 14-15; pg. 3323, right col., line 47-50). The film is chemically modified in order to attach the sample (pg. 3322, left col., line 47-57; pg. 3325, right col., line 12-13). The sample can be detected by light desorption mass spectroscopy (pg. 3322; left col., line 34-35). A signal enhancing agent is integrated with the sample (pg. 3326, left col., line 31-34). The sample is applied directly to the surface of the film (pg. 3323, right col., line 4-7).

Dale et al. differs from the claimed invention in failing to disclose the deposited thin film to be a columnar-void film.

Ebersole et al. disclosed a columnar-void film used as a biosensor detector (fig. 1; col. 7, line 33-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Dale et al. by including a columnar-void film as taught by Ebersole et al. for the practical advantage of providing the same surface to be used for analysis of multiple analytes regardless of the type of analyte (Ebersole et al.: col. 4, line 42-45).

The features of remaining dependent claims are either well known alternative methods (see US Patent 4,384,957) for analyte purification (e.g. purification (claim 3); separation means (claims 18)), or constitute obvious variations in parameters which are routinely modified in the art (e.g. type of substrate (claim 6) or film (claim 7); deposition parameters (claim 8)) and which have not been described as critical to the practice of the invention.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following prior art teaches a method of chromatography separation: Crowder, III et al. (US Patent 4,384,957).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
April 11, 2002


MARY E. CEPERLEY
PRIMARY EXAMINER A.U. 1641